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10/590,765	08/24/2006	Greg P. Beer	47082-168USPX	2504

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NIXON PEABODY LLP
300 S. Riverside Plaza, 16th Floor
CHICAGO, IL 60606-6613

EXAMINER	
CARLSON, KOURTNEY SALZMAN	
ART UNIT	PAPER NUMBER
1724	
MAIL DATE	DELIVERY MODE
01/18/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,765	BEER ET AL.	
	Examiner	Art Unit	
	KOURTNEY R. SALZMAN	1724	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-6,9-11,21-32 and 37-39* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-6,9-11,21-32 and 37-39* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed December 7, 2011 has been entered.

2. Claims 1, 21 and 38 have been amended.

3. Claims 1-6, 9-11, 21-32 and 37-39 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 21, 22, 25, 26, 30-32 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by GUO et al (US 6,033,866).

Regarding claims 1 and 39, GUO et al teaches a biosensor electrode with a reagent layer 16 comprising an enzyme and second redox compound wherein the mediators or redox compounds can be found as mixtures (c. 6, l. 28-42). The mediator and internal reference are taught in column 6, lines 28-42 to be any number of combinations which inherently will nearly all have different redox potentials. Just the reagent layer is utilized to teach the presence of both mediators and both the mediator and internal reference are therefore present in a single layer. The reagent layer 16 is shown to be on the surface of the electrode surface 22 in figure 1D.

Regarding claim 2, in column 2, line 52 of GUO et al, ferrocyanide is identified as a possible internal reference species, known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential, including that of the list of mediator components in column 6, l. 28-42.

Regarding claim 21, GUO et al teaches a biosensor with a reagent layer 16 comprising an enzyme and second redox compound wherein the mediators or redox compounds can be found as mixtures (c. 6, l. 28-42). The mediator and internal reference are taught in column 6, lines 28-42 to be any number of combinations which inherently will nearly all have different redox potentials. Just the reagent layer is utilized to teach the presence of both mediators and both the mediator and internal reference are therefore present in a single layer. The reagent layer 16 is shown to be on the surface of the electrode surface 22 in figure 1D. The term batch is interpreted to mean that the pieces are brought together on the sensor wherein the batch is the necessary pieces of one sensor for example. Moreover, since each tangible piece is present discretely they are inherently added separately or in batch.

Regarding claims 22 and 30-32, in column 2, line 52 and column 6, lines 40-44 of GUO et al, ferrocyanide is identified as a possible internal reference species,

known in the art to be a reduced form of a reversible redox couple. In combination with the ferrocyanide, numerous mediators can be utilized which have a lower redox potential from the list of possible mediators in column 6, lines 25-40. Moreover, ferricyanide is also identified in the opposite mediator mixture of GUO et al, as discussed in column 5, lines 13-20 as being a possible mediator. The substitution of any known mediator for another would be obvious as it would allow the same predictable functionality of electron transfer. This combination with the ferrocyanide would render equal redox potentials.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the method of making the sensor. Since the same materials (the numerous oxidizable species and mediators of use in GUO et al) and method of making are present as the internal reference and mediator as required by claim 21, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

6. Claims 21-22, 30-32 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by HODGES et al (US PG PUB 2001/0052470).

Regarding claims 21, 30, 31 and 32, HODGES et al teaches a biosensor with reagent mixture comprising an enzyme (GOD), ferricyanide (mediator) and ferrocyanide (internal reference) in paragraph 9. The specification of the instant application discloses the internal reference can be a mediator species on page 3,

line 24 of the instant application and this combination is taught on pages 15 and 16 of the specification as working in accordance with the present invention. Therefore, ferrocyanide can be interpreted to function as the internal reference. The chemical application or batch formation is discussed in paragraphs 69-70. The first sentence of paragraph 70 teaches the application of the chemicals on the surface of the electrodes themselves.

Regarding claim 22, the example of ferrocyanide as the internal reference and ferricyanide as the mediator is described on pages 15 and 16 of the specification to redox at the desired potentials.

Regarding claim 38, paragraph 70 of HODGES et al discloses the use of only one enzyme in the mixture.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 3-6, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of BLOCZYNSKI et al (US 5,520,786).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 6, lines 28-43 and column 5, lines 12-20.

Regarding claim 3, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. nickelocene or any of the other oxidized listed components of GUO et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 4, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claims 5 and 6, since the same materials are present as the internal reference and mediator, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself. For the purpose of this apparatus claim, the biosensor would be capable of reacting with the potentials as sufficiently required by the claim, as these are inherent reactions which the biosensor will perform when the process conditions specified are applied.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (i.e. any of the other oxidized listed components of GUO et al or any other identified electron transfer agent) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 24, GUO et al teaches the ferrocyanide to be present as the internal reference.

9. Claims 9-11, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over GUO et al (US 6,033,866), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

GUO et al teaches all the limitations of claim 1, including the use of numerous mediators as the mediator of the instant application in column 6, lines 28-43 and column 5, lines 12-20.

Regarding claims 9 and 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (i.e. any of the other oxidized listed components of GUO et al or any other identified electron transfer agent) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (GUO et al, c. 2, l. 5-9)

Regarding claim 10 and 28, GUO et al teaches the ferrocyanide to be present as the internal reference.

Regarding claim 11, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 as does GUO et al in column 2, l. 32-33.

10. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES (US PG PUB 2001/0052470), in view of BLOCZYNSKI et al (US 5,520,786).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 23, BLOCZYNSKI et al teaches the use of mediator 3-phenylimino-3H-phenothiazine in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (3-phenylimino-3H-phenothiazine, BLOCZYNSKI et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (Summary of invention and column 1, lines 47-50, BLOCZYNSKI et al)

Regarding claim 24, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed in the above rejection.

Regarding claims 25 and 26, these claims are directed to the method of operating the sensor while they depend of claim 21 which is directed to the method of making the sensor. Since the same materials and method of making are present as the internal reference and mediator as required by claim 21, the biosensor would function just as required when electronics outside the sensor supply the two potentials to the sensor itself.

11. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over HODGES et al (US PG PUB 2001/0052470), in view of NAGAKAWA et al (US PG PUB 2004/0245121 A1).

HODGES et al teaches all the limitations of claim 21.

Regarding claim 27, NAGAKAWA et al teaches the use of a Ru complex mediator with substitutions, or ruthenium hexamine, as discussed in column 3, line 57- column 4, line 9.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute the known mediator (ruthenium hexamine, NAGAKAWA et al) for another known mediator (ferricyanide, HODGES et al) because they would both yield the predictable result of functioning as an electron transfer agent in the reaction. (NAKAGAWA et al, c. 1, l. 37-46)

Regarding claim 28, HODGES et al teaches the ferrocyanide to be present as the internal reference, as discussed the above rejection.

Regarding claim 29, HODGES et al teaches the enzyme to be GOD or glucose oxidase in paragraph 9. Furthermore, NAGAKAWA et al teaches the use of the mediator with glucose oxidase for glucose measurements in column 4, lines 19-29 but will also be effective with any oxidation-reduction enzyme, as in HODGES et al.

12. Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GUO et al (US 6,033,866).

Regarding claims 37 and 38, column 5, lines 61-63 teaches the use of only one enzyme system in the mixture. Moreover, example 4 teaches the system can be

of use with one ferrocyanide (that of the second mediator layer which can include mixtures) and one enzyme. In the alternative, the use of a GOD system, in place of a HRP and GOX, would be both obvious as both function with the listed mediators for the same functionality of glucose reactivity.

Response to Arguments

13. Applicant's arguments filed December 7, 2011 have been fully considered but they are not persuasive.

14. The applicant argues on page 7, with regard to claim 1, that the GUO et al reference doesn't teach the mixture formed on the surface of the electrode.

a. It is the examiner's interpretation that figure 1D shows exactly that. Upon assembly of the sensor, the reagent layer will be at least in portion in contact with electrode layer 22.

15. The applicant argues on pages 7-8 that GUO et al is a more complex sensor than that of the instant application and teaches away from a more complicated sensor.

b. This argument is irrelevant. The claim does not limit the sensor to be a less complex sensor nor does it limit the constituents of the sensor itself to have to be of fewer components, therefore this argument is outside the scope of the claim.

16. The applicant argues on page 8, with regard to claim 21, that the GUO et al reference doesn't teach the mixture formed on the surface of the electrode.

c. It is the examiner's interpretation that figure 1D shows exactly that. Upon assembly of the sensor, the reagent layer will be at least in portion in contact with electrode layer 22.

17. The applicant argues the interpretation of the term "batch", stating that "batch" is defined as "a quantity required for or produced as the result of one operation". Moreover, the applicant cites their own specification as to their definition of batch.

d. Firstly, the definition supplied via the dictionary in the exhibit submitted by the applicant does not in the interpretation of the examiner differentiate GUO et al from the instant application. Through the assembly of the sensor, or one operation, the amount of reagent required is supplied to the sensor for operation. This would inherently be the formation of the sensor and reagent in batch.

e. Secondly, the definition supplied by the applicant via the specification is not expressly a definition at all. The cited paragraph teaches that the reagent is formed upon printing and the formation of the impurity of the reduced form of the mediator. This will occur in GUO et al as the reagent is also printed and the formation of the reduced form of the mediator will inherently occur upon exposure. This too would cause a variance from batch to batch, just as the applicant's does.

18. The applicant also argues there is no ferrocyanide present prior to the application of the sample in HODGES at the bottom of page 9 to page 10.

f. Firstly, the applicant is arguing that the relied upon paragraph 9 of HODGES et al teaches the ferrocyanide or internal reference equivalent is not

present prior to reaction, yet HODGES et al explicitly states in that same paragraph, "Ideally there is initially no ferrocyanide, although in practice there is often a small quantity". This small quantity fulfills the claim, as it is the presence of both mediators upon formation of the reagent, in a single layer, as the oxidation of the ferricyanide would inherently occur upon formation of the reagent itself.

19. The applicant argues that this impurity of HODGES et al which develops cannot read on that of the instant application as, "this has nothing to do with the formation of the claimed batch that is placed on at least partially on a surface of the working electrode and the counter electrode of the biosensor prior to the introduction of the fluid sample".

g. The examiner argues that this is exactly what it has to do with. The claim regards the pieces of the mixture to be added separately to form a batch of mixture. This is exactly what is happening upon the formation of the ferrocyanide present. The ferricyanide is added then its oxidation "separately" (as required by the claim) forms the next constituent of the reagent, all occurring prior to the introduction of the sample. If these pieces inherently happen, prior to the application of the sample, then this is exactly what the claim is attempting to cover in scope and patent coverage.

20. The applicant has argued that HODGES et al is confusing as paragraphs 69 and 70 at different times cite different mediator materials to be of use and even allege possible typos.

h. These paragraphs are not utilized by the examiner to teach materials of the mixture, but rather to just show that the pieces and sensor can be assembled in any number of ways including that of the separate pieces added for batch deposition, as in the instant application.

21. The arguments of claim 39 are addressed in the response to arguments of claim 1 as this claim is addressed by GUO et al in rejection and shares the same issues.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is

(571)270-5117. The examiner can normally be reached on Monday to Thursday 6AM - 4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

krs
1/12/2012

/KAJ K OLSEN/
Primary Examiner, Art Unit 1724